

## **REMARKS**

Claims 1-7, 9, 15, 16, 22, 30, and 31 are currently pending in the application. Claim 1 is the only claim in independent form.

Applicants express their gratitude for courtesies extended by the Examiner during a personal interview conducted with Applicants' representatives on June 2, 2004. During the personal interview, proposed amendments to the claims were discussed in view of all outstanding rejections. The Examiner had indicated that in view of additional amendments to the claims, the claims would be patentable over the prior art and all rejections under 35 U.S.C. § 112 would be overcome.

The presently pending claims have been amended pursuant to the Examiner's suggestions provided in the outstanding Office Action and the personal interview. Specifically, independent claim 1 has been amended to clarify the intended subject who has blocked immunization. In other words, the individual is "incapable of an immune response to a pathology."

Specifically referring to the Office Action, claims 1-7, 9, 15-16, and 22 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. According to the Office Action, the phrase "unblocking immunization" is not enabled by the specification. According to the Office Action, the breadth of the phrase "unblocking immunization" is unclear and would appear to potentially encompass methods well beyond what is enabled by this specification. As a result, undue experimentation to practice the claimed invention would be required.

The presently pending claims are enabled by the specification. The phrase "unblocking immunization" is defined in the specification on page 9, lines 1-19. More specifically, the phrase "unblocking immunization" is defined as the unblocking of the accumulation of dendritic cells, which have ingested or processed tumor antigens but are unable to mature. In other words, the inability to mature is the "blocked

immunization.” Unblocking immunization is achieved by the claimed step of promoting differentiation and maturation of immature dendritic cells in a regional lymph node and allowing presentation by resulting mature dendritic cells of antigen to T-cells to gain immunization of the T-cells to the antigen occurs.

In addition to the phrase being defined in the specification, methods for unblocking immunization are further supported in the Examples section of the present application. The Examples prove and therefore enable the scope of the presently pending claims. Therefore, the presently pending claims are fully enabled by the specification of the present application. Reconsideration of the rejection is respectfully requested.

Claims 1-7, 9, 15-16 and 22 have also been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. According to the Office Action, the claims have been rendered indefinite by the phrase “unblocking immunization.” According to the Office Action, the phrase should be more definitely defined in the claims.

The phrase “unblocking immunization” is defined in the specification of the present application. As set forth above, unblocking immunization is defined in the specification on page 9, lines 1-19. More specifically, the phrase “unblocking immunization” is defined as the unblocking of the accumulation of dendritic cells, which have ingested or processed tumor antigens but are unable to mature. In other words, the inability to mature is the “blocked immunization.” Unblocking immunization is achieved by the claimed step of promoting differentiation and maturation of immature dendritic cells in a regional lymph node and allowing presentation by resulting mature dendritic cells of antigen to T-cells to gain immunization of the T-cells to the antigen occurs. Because this phrase is clearly defined in the specification, the scope of the claims is not indefinite. Reconsideration of the rejection is respectfully requested.

Claims 2-7, 9, 15, and 16 have also been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. According to the Office Action, the phrase “natural cytokine mixture” is indefinite because the limitations of this phrase are unclear. In response thereto, the natural cytokine mixture has been clearly defined in the specification of the present application. More specifically, the natural cytokine mixture includes IL-1, IL-2, IL-6, IL-8,  $\delta$ IFN and TNF $\alpha$ . (See, page 7, lines 28-29). Since the natural cytokine mixture phrase has been clearly defined, it cannot render the presently pending claims to be indefinite. Reconsideration of the rejection is respectfully requested.

Claim 22 has also been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the use of trademarks/trade names in the claims. In response thereto, claim 22 has been amended and reconsideration of the rejection is respectfully requested.

Claim 1 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Banchereau, et al. According to the Office Action, the Banchereau, et al. reference teaches that immature dendritic cells differentiate and mature *in vivo* when exposed to antigens. Thus, the Office Action holds that exposure to antigens promotes (with the assistance of endogenous factors) the maturation and differentiation of immature dendritic cells into mature antigen-presenting cells. Moreover, the Office Action holds that when an antigen has previously been introduced into a subject in such a manner that it contacts an immature dendritic cell in a regional lymph node, it would have inherently promoted the maturation and differentiation of the cells therein.

As is well established, “[a]nticipation under 35 U.S.C. [§] 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention.” *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (Fed. Cir. 2000), citing, *Electro Med. Sys. S.A. v. Cooper Life*

*Sciences*, 34 F.3d 1048, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994)(emphasis added). Further, anticipation of the claims can be found only if a reference shows exactly what is claimed; where there are differences between the disclosures of the references and the claim, a rejection must be based on obviousness under Section 103. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed.Cir. 1985). Additionally, “[f]or a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference.” *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)(emphasis added).

Presently pending independent claim 1 is patentable and is not anticipated by the Banchereau, et al. reference. The method of “unblocking immunization” at a regional lymph node is not at all disclosed or suggested in the Banchereau, et al. reference. As set forth above, the phrase “unblocking immunization” is defined as the unblocking of the accumulation of dendritic cells, which have ingested or processed tumor antigens but are unable to mature. In other words, the inability to mature is the “blocked immunization.” Unblocking immunization is achieved by the claimed step of promoting differentiation and maturation of immature dendritic cells in a regional lymph node and allowing presentation by resulting mature dendritic cells of antigen to T-cells to gain immunization of the T-cells to the antigen occurs. This specific limitation is not at all disclosed in the Banchereau, et al. reference. The Banchereau, et al. reference discloses a method of inducing a primary immune response or immunological tolerance (See, Abstract). More specifically, the Banchereau, et al. reference discloses a method of inducing immunity in an unblocked condition. In contradistinction, the claimed invention relates to a method of “unblocking immunization” by promoting differentiation and maturation of immature dendritic cells in a regional lymph node and allowing presentation by resulting mature dendritic cells of antigen to T-cells to gain immunization of the T-cells to the antigen. This is a different method than that disclosed in the Banchereau, et al. reference. In fact, the Office Action holds that the Banchereau, et al. reference only inherently promotes maturation and differentiation of cells. Since this is not “unblocking immunization” as claimed in

the presently pending independent claim 1, the Banchereau, et al. reference cannot anticipate the presently pending independent claim 1.

In summary, the specific limitation of “unblocking immunization” is not at all disclosed in the Banchereau, et al. reference. Since this particular phrase is not disclosed or suggested by the Banchereau, et al. reference, presently pending independent claim 1 is not anticipated by the cited prior art reference as a matter of law. As a result, reconsideration of the rejection is respectfully requested.

The present amendment places the present application in condition for allowance, which allowance is respectfully requested. If any remaining issues exist, Applicants respectfully request to be contacted by telephone at (248) 539-5050.

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Respectfully submitted,

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